UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/341,590	07/13/99	LARSEN B	PPT-20479-US

HM12/0207

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EXAMINER	
LUKTON, D	
ART UNIT	**PAPER NUMBER**
1653	18

DATE MAILED: 02/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/341,590	Due Larsen
Examiner	**Group Art Unit**
David Lukton	1653

☒ Responsive to communication(s) filed on *Jan 18, 2001*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-32, 37, 39, 41, 43, 45, 47, and 49* is/are pending in the applicat

Of the above, claim(s) *39, 41, 43, 45, 47, and 49* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-32 and 37* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Claims 1-32, 37, 39, 41, 43, 45, 47, 49 remain pending.

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This application contains sequence disclosures that are encompassed by the definitions for amino acid sequences set forth in 37 CFR 1.821. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 with regard to the sequence disclosures.

As indicated previously, further sequence listings are required. The claims encompass conjugates in which "X" can be any of the following:

> enkephalin, Leu-enkephalin, Met-enkephalin, endothelin, vasoactive intestinal peptide, substance P, neurotensin, endorphin, insulin, gramicidin, paracelsin, delta-sleep inducing peptide, angiotensin-I, angiotensin-II, angiotensinogen, angiotensinogen, vasopressin, oxytocin, calcitonin, calcitonin gene-related peptide, calcitonin gene-related peptide-II, parathyroid hormone (1-34), parathyroid hormone related peptide, EMP-1, atrial natriuretic peptide, brain natriuretic peptide, C-type natriuretic peptide (1-53), "mini-ANP", cecropin, kinetensin, neurophysins, elafin, guamerin, atriopeptin-I, atriopeptin-II, atriopeptin-III, deltorphin-I, deltorphin-II, vasotocin, bradykinin, dynorphin, dynorphin-A dynorphin-B, GRH, GH releasing factor, GH releasing peptide, growth hormone, tachykinin, ACTH, cholecystokinin, corticotropin releasing factor, diazepam binding inhibitor fragment, FMRF-amide, leupeptin, sandostatin, galanin, gastric releasing peptide, gastric inhibiting polypeptide, glucagon, glucagon-like peptide -1, glucagon-like peptide-2, exendin-3, exendin-4, LHRH, melanin concentrating hormone, melanocyte stimulating hormone, alpha-MSH, morphine modulating peptide, somatostatin, substance K, TRH, Kyotorphin, melanostatin, hirulog, hirulog-1, melanotan-II, thymosin alpha-1, ornipressin, octreotide, motilin, neurokinin-A, neurokinin-B, neuromedin B, neuromedin C, neuromedin K, neuromedin N, neuromedin U, neuropeptide K, neuropeptide Y, PACAP, pancreatic polypeptide, peptide YY, peptide histidine methionine amide, secretin, thrombopoetein, insulin-like growth factor-I, insulin-like growth factor II, GHRP-6, interleukin-II, beta-interleukin-I, beta-interleukin-II, epidermal growth factor (20-31), eptifibatide, endomorphin-1, endomorphin-2, adrenomodulin, antiarrhytmic peptide, antagonist G, indolicin, osteocalcin, cortistatin-29, cortistatin-14, PD-145065, PD-142893, fibrinogen binding inhibitor peptide, leptin 93-105, GR 83074, and Tyr-W-MIF-1.

A sequence listing has been provided for many of these; however, applicants have failed to provide a sequence listing for all of them. A sequence listing is required for each of the

foregoing peptides (that has not already been provided). The sequence listing will aid in the search.

A first action on the merits is issued herewith; however, this issue remains.

Applicant is given the time period set in this letter within which to comply with the sequence rules, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period.

*

Pursuant to the restriction, claims 39, 41, 43, 45, 47, 49 are withdrawn from consideration.

The elected specie is Leu-enkephalin-$(Lys)_6$. As stated by applicants, claims 1, 2, 6-12, 19, 20, 24-26, 29-32, 37 encompass the elected specie, and claims 3-5, 13-18, 21-23, 27, 28 do not. At the present time, none of claims 3-5, 13-18, 21-23, 27, 28 is withdrawn from consideration. However, those claims which do not encompass the elected specie may be withdrawn at a later time.

Claims 1-32, 37 are examined in this Office action.

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and

using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 37 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 37 is drawn to a method of inhibiting neurons from transmitting pain impulses to the spinal cord. However, there is no evidence that this is the case.

*

Claims 1-32, 37 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 6, the phrase "such as" fails to set the metes and bounds.

Claim 6 should be limited to one range; claims dependent on claim 6 may of course be added. It is suggested that claim 6 be limited to a range of 4-15 amino acids; a dependent claim can then be added which recites 4-10 amino acids. See also claims 9, 10, 21, 23.

In claim 19, "Xaa" is undefined in many of the sequences.

*

The following is a quotation of the appropriate paragraphs of 35 U.S.C §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2) and (4) of section 371(c) of this title before the invention thereof by the applicant for the patent.

Claims 1-2, 19, 24 are rejected under 35 U.S.C. §102(b) as being anticipated by Neer (USP 4,833,125).

Neer teaches col 2, line 4+ that the first 26 amino acids of the peptide set forth in col 4, line 60+ are "active". As indicated (col 4, line 60+), the amino acid sequence at positions 20-34 is the following:

RVEWLRKKLQDVHNF

Thus, the PTH(1-34) can be viewed as a "conjugate" between PTH(1-26) and the peptide "KLQDVHNF". Instant claim 1 requires that "Z" contain 4 amino acids. The peptide PTH(1-34) can thus be viewed as consisting of three parts: (a) the first 26 amino acids of PTH, which are asserted to be active, (b) the tetrapeptide "KLQD", and finally (c) the tetrapeptide "VHNF". Viewed another way, the PTH(1-34) can be viewed as a conjugate which "comprises" the first 26 amino acids, and the tetrapeptide "KLQD". Since the claimed conjugate "comprises" anything, the peptide in question could consist of 34 amino

acids, or 3400; there would be no difference from the perspecitive of the applicability of the reference in a §102 rejection. Instant claim 1 permits "Z" to contain each of the four amino acids present in "KLQD". Claim 24 is anticipated because it includes any "truncated analog" of PTH(1-34).

Accordingly, the claims are anticipated.

*

Claim 1 is rejected under 35 U.S.C. §102(b) as being anticipated by Katz (USP 5,716,614) or Ryser 4847240

Katz and Ryser both teach conjugates of polylysine and biologically active peptides.

Thus, the claim is anticipated

*

Claims 1-3 are rejected under 35 U.S.C. §102(b) as being anticipated by Larsen (WO 98/11126).

Larsen teaches conjugates of the following formula:

X-L-Z

where "X" is a pharmacologically active peptide, "L" is a linker, and "Z" is a peptide

USP 4,542,124 was stricken from the IDS because this reference was not received.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton [phone number (703)308-3213].

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1800